

⑧
YES
Pilot
Contract

Suggestions to DISCUSSION DRAFT 2/19/01

1:

... with respect to an exploratory study ("Pilot Study") with humans to establish the validity of the design concepts (e.g. sample collection, feasibility and precision of analytical methods for biomarkers, sample handling and stability, data acquisition by questionnaire) to be used in a subsequent population study ("Total Exposure Study"). In particular the pilot study should determine the intra-and inter-individual variability of each estimate of smoke constituent uptake as a basis for the design of the Total Exposure Study and if the selected biomarkers of exposure and effect can differentiate between smokers of 3.0 to 6.9 mg tar (FTC) cigarettes and non-smokers.

2:

The most recent draft of the protocol will be provided by COVANCE not later than March 9, 2001.

3:

... e.g. draft advertising, informed consent form, questionnaires, diaries, [Hans]

7:

March 31, 2002

12:

...to the protocol, questionnaires, diaries, CRF, data and databases without subject name identification, reports.